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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,503	09/13/2001	Robert-Peter Klein	512100-2022	6117

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/936,503

Applicant(s)

KLEIN ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

### DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment and Response filed 5/12/03.

#### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 7 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (USPN 5,820,876) in view of Nichols (USPN 4,804,541). Claims 7 – 12 are drawn to a transdermal therapeutic system (TTS) comprising a drug impermeable backing layer, a drug depot, a matrix, which contains the drug depot, and a pressure sensitive fixing device. The matrix and/or the drug depot comprise paper as a support material. The TTS delivers various active compounds including nicotine, lidocaine and sexual hormones. Claims 10 – 12 are recite limitations to the weight of the paper used in the matrix and/or depot. Claims 13 and 14 are drawn to a process of manufacturing the device of the invention comprising applying the active agent to the support paper.

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Hoffman et al teaches a TTS with a backing layer, drug depot, and matrix, which encompasses the drug depot. The TTS further comprises a pressure sensitive adhesive, which adheres to the skin. The drugs and active agents delivered by the TTS ranges from nicotine to sexual hormone like progesterone and thymoleptics like scopolamine (hydrobromide) (col. 3, lin. 23 – 67; Fig. 1 – 3; col. 5, lin. 24 – col. 6, lin. 22). The reference however does not disclose a paper support material for the matrix.

Nichols et al teaches a TTS with a backing material impermeable to the active agents. The TTS further comprises a pressure sensitive adhesive component that affixes to the skin and a matrix component that contains the active agents. The matrix material is can be made of absorbent paper. The active agent of the invention is the sexual hormone estradiol (col. 2, lin. 15 – 29; lin. 57 – 65; col. 3, lin. 3 – 11).

With regard to claims 10 – 12, the specific weight of the paper used as a support for the active agent would be determined through routine experimentation by one of ordinary skill in the art. A skilled artisan would be able to determine the optimal weight of paper in order to maximize the absorption of the active agent and the delivery of the agents. Regarding claims 13 and 1, a skilled artisan would be able to modify the amount of the active agent applied to the substrate. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various transdermal compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at

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the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With this in mind one of ordinary skill in the art would have been motivated to combine the teachings and suggestions in the art. As skilled artisan would have been motivated to substitute the matrix of Nichols into the structure of Hoffman in order to improve the transmission of the active agent, specifically estradiol. It would have been obvious to combine these teachings since they both deliver sexual hormones transdermally. It would have been obvious to combine these teachings as such with an expected result of a TTS device with a paper-supported matrix that delivers estradiol.

#### ***Response to Arguments***

1. Applicant's arguments filed 5/12/03 have been fully considered but they are not persuasive. Applicant argues that:

- a. Hoffman does not teach the use of paper as a support.
- b. Nichols does not solve these deficiencies.
- c. There is no motivation to combine the references.

The TTS delivers nicotine and possibly sexual hormones. The matrix material is recited to be cellulose based, which can be fibrous. Paper is not mentioned, as a matrix material, yet the suggestion of cellulose-based fibrous material is there. This reference does not need to encompass each and every element of the claimed invention since it is applied under § 103 and need only suggest the elements to obviate the claimed invention. Nichols discloses a TTS where the carrier material is listed as absorbent paper, along with similar other carrier material as

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listed in Hoffman. Nichols also delivers estradiol, a sexual hormone. Nichols provides the appropriate support material to Hoffman's structure. It is not necessary for Nichols to contain a drug depot, since it is merely a supportive reference showing the level of skill in the art to use paper material as carrier components in TTS. It would have been obvious to a skilled artisan to combine the teachings since both transdermal devices delivered sexual hormones, and comprised similar structural components (i.e. impervious backing layer, medicament layer, etc.). It is the position of the examiner that this combination would have been obvious and this combination of teachings continuous to obviate the claimed invention.

***Conclusion***

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005.

The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

MP Young  
July 23, 2003

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1500